made available to patients. The objective of this abstract is to highlight the difference of data requirements between the EMA and some of the main HTA bodies, and the subsequent outcomes in terms of access and reimbursement decisions. **METHODS:** The list of medicines under CA status was downloaded on March 16th 2015 from the EMA website.2 For each medicine, advice from the National Institute for Health and Care Excellence (NICE), Scottish Medicines Consortium (SMC), National Authority for Health (HAS) and Federal Joint Committee (GBA) was taken from the agencies' websites.3 The HTA outcomes were measured from final recommendation in the UK, the medical benefit (SMR) and improvement in medical benefit (ASMR) scores in France and the level of additional benefit in Germany. Medicines approved after March 2014 (n = 3) and vaccines (n = 2) were excluded. **RESULTS:** 77% of the selected medicines had at least one unfavourable HTA outcome (defined as no or restricted recommendation in the UK, SMR lower than substantial and/or ASMR V in France, no or unquantifiable additional benefit in Germany). 50% had a majority of unfavourable HTA outcomes. **CONCLUSIONS:** Although the EMA seems to have accelerated patient access to selected medicines, it does not actually translate into patient accessibility as regulators and payers have a different perception on the benefits these medicines offer. Greater alignment between regulators and payers is needed for patients. 1Article 14(7) of Regulation (EC) No 726/2004; 2http://www.ema.europa.eu/ema/; 3http://www.has-sante.fr/portail/jcms/r_1500918/en/les-avis-sur-les-medicaments, http://www.english.g-ba.de/, https://www.nice.org.uk/, https://www.scottishmedicines.org.uk/Home

PHP241

A HANDBOOK AND A TOOLKIT FOR HOSPITAL-BASED HEALTH TECHNOLOGY ASSESSMENT

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OBJECTIVES: Hospitals need a formalized system to introduce new health technologies. Hospital-based HTA (HB-HTA) units can provide relevant and timely information to decision makers. However, to date no comprehensive body of knowledge of current practices and tools exists to guide how to set up these units in hospitals. AdHopHTA, a European research project funded by the FP7, aims to gather information and knowledge and develop these tools. Therefore, our objectives are to present the handbook and web-based toolkit for HB-HTA developed by the AdHopHTA project, which aims to guide and facilitate the setting-up and the daily work (e.g. assessments) of an HB-HTA unit. **METHODS:** AdHopHTA has used a multi-method approach to develop the content of the handbook and toolkit including 6 literature reviews, 107 face-to-face surveys, 40 case studies, 1 large-scale survey, 1 focus group, 1 Delphi process, 1 validation workshop and several Steering and Advisory Committee meetings. In total 375 people from 20 different countries have provided their input. **RESULTS:** The handbook presents the informational needs and organizational models of HB-HTA units in Europe. It also describes the positive impact of HB-HTA in the adoption of new health technologies in hospitals and how to create a comprehensive HTA ecosystem through the interaction between national or regional HTA organizations and HB-HTA units. 15 guiding principles for good practices in HB-HTA are also presented using current examples from existing HB-HTA units. The Toolkit is built based on these guiding principles. It consists of practical guidance grouped into four dimensions (the assessment process; leadership, strategy and partnerships; resources and and impact). It includes proposed solutions to potential problems as well as specific tools (e.g. AdHopHTA mini-HTA template) for each dimension. **CONCLUSIONS:** The AdHopHTA Handbook and Toolkit are support instruments for designing, setting-up and running HB-HTA units.

PHP242

THE CEESP ECONOMIC EVALUATION: CAN CLINICAL EFFICACY AND COST-EFFECTIVENESS CO-EXIST IN FRANCE

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OBJECTIVES: The Commission for Economic Evaluations and Public Health (Commission Evaluation Economique et de Santé Publique, (CEESP)) has been conducting health economic evaluations since 2008. Due to continued economic pressure, as of October 2013, manufacturers are required to submit an economic evaluation to the CEESP under certain conditions, in addition to the Commission de Transparence's existing clinical assessment. The objective of this analysis was to gain a better understanding of the drivers of positive and negative CEESP decisions. **METHODS:** All publically available CEESP decisions were retrieved from the agency's website in April 2015. The CEESP evaluates submissions against the HAS' pharmacoeconomic guidelines, in which areas of weakness are identified through a system of "reserves" rather than a strict ICER threshold. Data was extracted to determine the number of and rationale for minor, important, and major reserves awarded by CEESP to the manufacturer's submission, as well as accepted incremental cost-effectiveness ratios. **RESULTS:** According to HAS's methodological guide for economic evaluations, cost-effectiveness should be considered alongside clinical efficacy. At the time of analysis, four CEEPS appraisals were publically available. 50% of submissions had ICERs above 100,000 EUR per QALY gained, and based on findings to date, no firm ICER threshold was apparent. 50% of submissions were found to have minor, important, as well as major reserves. Our analysis revealed 5 key factors to improve the chance of a positive CEESP review: (1) A clearly presented analysis with a validated model structure; (2) a submission that satisfies the HAS guidelines; (3) a proper justification of all model inputs and assumptions; (4) an appropriate comparator; (5) a consideration of the "national factor". **CONCLUSIONS:** CEESP appraisal has only recently emerged as a market access requirement in France; continuous monitoring will be needed to better understand positive and negative drivers of decisions.

PHP243

CONSUMER INTEREST IN ADOPTING AN ELECTRONIC HEALTH RECORD (EHR) MOBILE APPLICATION BASED ON THE RISK THAT IDENTIFIABLE INFORMATION IS LEAKED

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OBJECTIVES: This study was designed to understand consumer interest in a mobile application designed to allow individuals to view their personal health record on a mobile device, and to share their health records with someone else if they choose. As a secondary objective, this study evaluated the likelihood of consumers to use the device based on the varying risk of a leak of their identifiable information (risk tolerance). **METHODS:** A representative (U.S.) sample of 1,000 adults completed an online survey about their interest in an EHR mobile application. Interest in the application was elucidating using a 7-point Likert scale and a standard gamble (SG) exercise. **RESULTS:** Prior to any indication of a potential privacy risk, 31% of consumers indicate they would be very likely to download an EHR mobile application (rated 6 or 7 on 7-point Likert scale; 4.0 mean). Nearly half (44%) of those who do not expect to use the app indicate they have privacy concerns. Based on the SG, only 50% report they would download the mobile application if there was a 95% chance their data was completely secure. Expected use of the application declines rapidly; 39% would use it if there was a 90% chance their data was completely secure and 31% would use it if there was an 85% chance their data was completely secure. Only 3% are still interested in the application with only a 5% chance their data was completely secure. **CONCLUSIONS:** There is a sizeable market for EHR mobile applications. Up to half of consumers report interest in using an EHR mobile application; and yet, there are important data concerns. Particularly given large-scale data breaches of large organizations, it will be critical for developers to quell fears of potential users of a data leak.

PHP244

AN ANALYSIS OF GERMAN G-BA ADDED BENEFIT ASSESSMENT DECISIONS USING THE WORLD HEALTH ORGANIZATION DALY FRAMEWORK

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OBJECTIVES: Since January 2011, the German G-BA has evaluated new drugs on their degree of added benefit versus a comparator therapy. We used disease-specific Disability Adjusted Life Years (DALYs), reported by the World Health Organization (WHO) as the sum of Years of Life Lost from mortality (YLL) plus Years Lost due to Disability (YLD), to help explain G-BA benefit assessment decisions. **METHODS:** EMA-approved drugs (January 2010-June 2015) were identified from European Public Assessment Reports (EPARs) and cross-referenced with the G-BA website to create an analysis set of drugs that have received benefit assessment ratings. Drugs with EMA orphan-drug designation were excluded. We defined Added Benefit (AB) as drugs that received G-BA ratings of "considerable", "low", or "unquantifiable" benefit in any patient subgroup, and No Added Benefit (NAB) as drugs only receiving ratings of "no additional benefit" and "inferior". Using WHO-reported German 2012 DALYs, proportions of YLLs and YLDs for each drug's lead indication were calculated: Drugs for diseases in which YLLs >75% of the DALY were defined as High Mortality Drugs (HMD); drugs for all other diseases were Low Mortality Drugs (LMD). We then predicted the odds of receiving AB versus NAB based on this new metric. SPSS was used to perform Fisher's exact test and to generate Odds Ratios (OR). Sensitivity analyses were performed on the %YLL threshold definition. **RESULTS:** From 373 EPARs, we identified 73 non-orphan drugs receiving G-BA benefit assessment ratings, 58 of which had matched DALY data for the lead indication. Of these 58 drugs, 35 were indicated for HMDs while 23 had LMD indications. 30 of 35 (86%) HMDs received an AB rating while only 4 of 23 (17%) LMDs received an AB rating ($p<0.001$, OR: 28.6). **CONCLUSIONS:** Our analysis suggests that in Germany there may be a demonstrated and predictable bias for drugs for fatal diseases.

PHP245

ROMANIA'S NEW HTA SYSTEM: WHAT PROGRESS HAVE INNOVATIVE DRUGS MADE UNDER THE POINTS-BASED SYSTEM SO FAR?

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OBJECTIVES: To assess the progress of a large group of innovative drugs evaluated recently under the HTA system introduced in Romania in 2014, which is the mechanism now used to reach decisions on which new medicines are included on the reimbursement list. **METHODS:** A systematic study of the HTA decisions already taken by the department for health technology assessment of the Romanian drug agency was undertaken, to ascertain the number of medicines / indications approved for unconditional reimbursement (not requiring cost-volume contracts), conditional reimbursement (requiring cost-volume contracts) and those not qualifying for reimbursement. Patterns were sought and identified among those drugs / indications which are awarded higher and lower points scores. **RESULTS:** Of the 144 HTA decisions, considering only originator medicines and their indications, there have been 23 recommendations for unconditional reimbursement, 51 recommendations for conditional reimbursement, and 70 recommendations for exclusion from reimbursement. Among the therapeutic areas and drug types in which unconditional reimbursement decisions are frequent are new oral anticoagulant drugs and type-2 diabetes drugs. Many older originator medicines have tended to receive lower points scores, not qualifying for reimbursement. **CONCLUSIONS:** The HTA points system in Romania is in its early stages but already some patterns are emerging from the combination of criteria used to accumulate points – including decisions by western European HTA bodies, the number of EU member states in which a drug is reimbursed, and the impact on the budget of the Romanian health insurer. With major legislative transformations underway in Romania's pharmaceutical pricing and reimbursement system, the real

impact of the HTA system will be revealed by the number of drugs recommended that are subsequently placed on the reimbursement list, and with what restrictions.

PHP246

DIRECT EVIDENCE VERSUS LACK OF DIRECT EVIDENCE AND THE IMPACT ON HTA ACCEPTANCE

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OBJECTIVES: Health technology assessment (HTA) agencies generally prefer the submission of direct evidence when appraising new interventions; however, an absence of head-to-head trial data is relatively common and indirect comparison is often required to determine relative effectiveness. To inform future submissions, acceptance rates across six HTA agencies were compared between submissions presenting direct evidence (active-comparator studies) and submissions lacking direct evidence. **METHODS:** All single HTA appraisals from 2014 for NICE (England), SMC (Scotland), CADTH (Canada), PBAC (Australia), IQWIG (Germany), and HAS (France) were included in the analysis, including resubmissions. Multiple technology appraisals, vaccination programmes, requests for advice, and submissions where the clinical evidence base was not described were excluded. The recommendation, reasoning behind the recommendation, and type of evidence presented were extracted. Fisher's exact test was used to test for statistical significance. **RESULTS:** In 2014, NICE accepted 92% (11/12) of all submissions presenting direct evidence versus 88% (7/8) of submissions lacking direct evidence, SMC accepted 79% (26/33) versus 87% (13/15), CADTH accepted 90% (9/10) versus 53% (10/19), PBAC accepted 50% (26/52) versus 82% (14/17), IQWIG accepted 48% (13/27) versus 13% (2/15), and HAS accepted 97% (42/43) versus 92% (35/38). A lack of direct evidence tended to be acceptable in cases where hard endpoints could be compared, and in disease areas with small patient numbers or a lack of therapeutic alternatives. Adjusted indirect comparisons were generally favoured over unadjusted comparisons, where presented. **CONCLUSIONS:** With the exception of IQWiG (p=0.025), acceptance rates for submissions reporting direct evidence were not significantly different to rates for submissions lacking direct evidence for each agency, although acceptance rates varied across HTA agencies. Single-arm or placebo-controlled trials continue to be viewed as acceptable clinical evidence by most HTA agencies when such study designs are justifiable, and when relative efficacy can be demonstrated through robust indirect comparison.

PHP247

HEALTH TECHNOLOGY ASSESSMENT ARCHETYPE: IMPLICATION ON LAUNCH PLANNING AND EVIDENCE SYNTHESIS

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OBJECTIVES: We aimed to quantitatively segment the health technology assessment (HTA) agencies into functional archetypes to sort countries with similar functional objectives and process into one group. **METHODS:** Through literature search, we developed a Likert scale comprising 77 question from 18 best practice principles, and 6 functional domains. Each question is marked on a scale of 0-5, with higher score (4 or 5) indicating best practice/ease of accession and low score (0 or 1) indicating lack of guidance/difficulty in accession. Our scale includes the key attributes of HTA process, i.e. general submission process, pharmacoeconomics, pricing, and evidence requirements under six functional domains: transparency, process, technical, equity, speed and implementation. **RESULTS:** We evaluated HTA guidelines and process of 66 HTA agencies worldwide, followed by scoring and weighted analysis. Using univariate analysis on total weighted score, we segregated the dataset into five percentiles, with definition reflecting functional objectives: 0-25% (Price Managers), 26-50% (Formulary Managers), 51-75% (Cost Advisors), 76-90% (Value Appraisers), and 91-100% (Value Implementers). Characteristically, Price Managers (eg. Singapore, India, Hong Kong) are free pricing markets, where setting drug price is the only hurdle in market access. Formulary Managers (eg. US, China) control drug price based on budget and regulatory approval. Cost Advisors (eg. Brazil, Mexico) are emerging HTA agencies that use HTA to advice cost. Value Appraisers (eg. South Korea, New Zealand) perform HTA on regular basis, but regional requirements overcome implementation of findings to drug price and reimbursement. Value implementers (eg. England, Canada, Germany) are the most mature markets, with pay for performance measures being the primary functional objective. **CONCLUSIONS:** Our analysis provides a new approach to quantitatively benchmark and group HTA agencies into archetypes based on functional objectives and local priorities. Analysis at domain and principle level helps mapping the similarity of requirements by each archetype, enabling evidence-based launch planning.

PHP248

EVALUATING THE SAFETY IMPACT OF LIGHT EMITTING DIODE (LED) GUIDED DRUG PICKING IN AN OUTPATIENT PHARMACY

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OBJECTIVES: Medication errors may occur during the drug picking process whereby the wrong drug, strength or quantity is picked. In May 2012, LED were installed and tagged to drug bins at the outpatient pharmacy in Singapore General Hospital with the intent to prevent these costly errors. Upon scanning a Quick Response (QR) code on the drug label, the LED corresponding to the drug bin will light up, signaling the picker to the correct drug bin. This study seeks to evaluate the safety impact of LED-guided drug picking and pharmacy staff's acceptance of this system. **METHODS:** The primary outcome of this study is the safety of the drug picking process measured in terms of the frequency of picking near misses. Near miss data before (January to April 2012) and after (May to August 2012) implementation of LED-guided drug picking were extracted electronically for statistical comparison. A survey was administered on pharmacy staff (n = 50) to find out their acceptance on drug picking with and without LED-guidance. Data from the survey were collated and analyzed descriptively. **RESULTS:** The implementation of LED-guided drug picking significantly reduced near misses for wrong drug [7.18 ± 3.17 vs 2.71 ± 1.36, p<0.001] and wrong strength [3.47 ± 2.48 vs 1.82 ± 1.13, p=0.02]. There was no significant difference in the frequency of picking near misses for wrong quantity [17.8 ± 9.88 vs 14.0 ± 4.64, p=0.162]. Overall, there was a significant reduction in the frequency of total picking near misses [28.4 ± 13.2 vs 18.1 ± 5.44, p=0.007]. Pharmacy staff's acceptance towards LED-guided picking was generally positive with majority preferring the LED over no LED-guided drug picking. **CONCLUSIONS:** Incorporation of LED into drug picking significantly decreased near misses of wrong drug and strength that potentially prevented costly medication errors. Pharmacy staff were generally receptive to LED-guided picking.

PHP249

EVIDENCE REVIEW GROUP (ERG) CRITIQUE OF SYSTEMATIC REVIEWS (SR) SUBMITTED TO NICE AS PART OF SINGLE TECHNOLOGY APPRAISALS (STA) OR MULTIPLE TECHNOLOGY APPRAISALS (MTA) IN THE LAST THREE YEARS

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OBJECTIVES: The aim of this review was to assess the critiques highlighted by the ERG for SR submitted to NICE by manufacturers as part of STA or MTA. **METHODS:** ERG reports available on the NICE website were systematically searched for the last three years (2013-2015). The ERG comments in the documents were carefully assessed along with the submission documents. Emphasis was placed on ERG comments regarding search strategy design, electronic databases used for article retrieval, inclusion/exclusion criteria in SR, and reporting of SR methodology. **RESULTS:** Fourteen ERG comment documents were identified by the search conducted in May 2015. Ten documents were identified in 2013, three in 2014, and one in 2015. Comments on search strategies, such as incorrect search terms, missing terms, and wrong explosion, were made on seven submissions. Major findings such as chances of omission of key studies, missing intervention synonyms, and improper presentation of search strategies were cited in two submissions. Two submissions did not search the minimum number of electronic databases indicated by NICE. ERG comments around SR inclusion/exclusion criteria were ambiguity in the study selection criteria, omission of the intervention of interest, selection of inappropriate follow-up duration, introduction of additional exclusion criteria at a later stage, exclusion of studies based on sample size, a clinically irrelevant primary outcome, exclusion of non-English studies even in cases of data gaps, and exclusion of some geographical subgroups without rationale. The write-up of SR was inadequate in two submissions because of ambiguity around the number of reviewers at each stage, unclarity around second check of extracted data, poor reporting of methodology, and an incorrect study selection flowchart. **CONCLUSIONS:** The ERG findings demonstrate a gap in manufacturer's search strategy design, rationale for inclusion/exclusion criteria, and writing-up of the SR methodology which has led to additional work while providing clarifications to NICE.

PHP250

EVOLUTION & INFLUENCE OF HTA IN EMERGING MARKETS

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OBJECTIVES: The objective of this study was to analyze the influence and development of 13 HTA bodies in select Emerging Markets. **METHODS:** This study examined 13 HTA bodies in Latin America (Argentina, Brazil, Colombia, and Mexico), Asia (Korea, Taiwan, China, Singapore, Malaysia, and Thailand), Africa (South Africa), Middle East (Saudi Arabia), as well as Central and Eastern Europe (Turkey). The countries were selected based on the diversity associated with the HTA evaluation process, and were assessed for their review timeline, influence on the pricing and reimbursement process, and anticipated future developments as indicated from their websites and other publications. **RESULTS:** Among the 13 selected HTA bodies, five countries (KOR, TWN, BRA, TUR, and ARG) have a defined review timeline; assessment outcomes will generally become available within a 1-year of submission. However, a standard timeline has yet to be defined for the rest of the countries. Four countries (KOR, TWN, BRA, and MEX) have formal HTA bodies, and assessments are mandatory in the pricing and reimbursement process. In other six countries (SGP, ARG, COL, THA, SAU, and TUR), HTA assessments may be considered in the pricing and reimbursement evaluation. For CHN / MYS / ZAF, although an HTA body is under development, it does not currently have any impact on the reimbursement decision-making. For future HTA developments, the focus remains on scope expansion, capability building, and international collaboration. **CONCLUSIONS:** Emerging markets have developed or are in the process of developing HTAs for the evaluation of formulary inclusion and as a method of cost containment. The HTA bodies in the selected emerging markets have varying impact over the pricing and reimbursement process. The ones with greater influence tend to have a defined review timeline and an HTA body that is a formal authority with a mandatory and / or influential assessment.

PHP251

ASSESSMENT OF CONSUMER LIKELIHOOD TO ADOPT AN ELECTRONIC HEALTH RECORD (EHR) MOBILE APPLICATION AND THE IMPACT OF PERCEIVED RISK OF PRIVACY LEAKS

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OBJECTIVES: This study was designed to understand consumer likelihood to adopt a mobile application designed to allow individuals to view their personal health record on a mobile device as a function of risk tolerance of private medical data leaks, including variability by various demographics. **METHODS:** A representative (U.S.) sample of 1,000 adults completed an online survey about their interest in an EHR mobile application. Interest in the application was elucidating using a 7-point Likert scale and a standard gamble (SG) exercise. The multivariate relationship between overall likelihood of mobile application use and SG utilities, education level, age, income level, and satisfaction with personal physician was assessed. **RESULTS:**